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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,941	04/30/2001	James F. Hemerick	6530.0278	8636

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1300 I STREET, NW
WASHINGTON, DC 20005

EXAMINER

THALER, MICHAEL H

ART UNIT	PAPER NUMBER
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3731

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DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/843,941

Applicant(s)

HEMERICK ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,45,47-57,59-65,67 and 68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,45,47-57,59-65,67 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Claims 11, 45, 48, 50-55 and 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Bartholf et al. (2001/0034549). Winston et al. show outer tubular structure 20, inner elongated structure 12, stent accommodating area (just distal to flange 14) and a plurality of external tubular structure contact areas (flanges 14) which slide against the interior surface of the outer tubular structure 20 since they are shown contacting one another in figures 1, 2 and 4. Winston et al. fail to disclose a translucent region at the distal end of the outer tubular structure 20. However, Bartholf et al. teach that the distal end region of the outer tubular structure of a stent delivery system should transmit light therethrough so that the stent therein may be visually inspected (paragraphs [0034] and [0037]). It would have been obvious to enable the distal end region of the outer tubular structure 20 of Winston et al. to transmit light therethrough so that it too would have this advantage. The Bartholf et al. distal end region 72 of the outer tubular structure is translucent and is non-braided as claimed, although it surrounds braiding 70. Further, the length of this translucent region substantially coincides with a constrained length of the stent as seen in figures 2 and 3. As to claims 48 and 50, Winston et al. fail to disclose at least

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one marker band on the inner elongated structure. However, Bartholf et al. teach that the inner elongated structure of a stent delivery system should include a marker band 22 in order to provide an indication of whether or not the stent has been completely deployed (paragraph [0031]). It would have been obvious to include a marker band on the on the inner elongated structure 12 of Winston et al. so that it too would have this advantage. As to claim 51, Winston et al. fails to disclose the steps of retracting the stent back into the outer tubular structure and then repositioning the stent delivery system. However, retracting the Winston et al. stent back into the outer tubular structure and then repositioning the stent delivery system when it is determined that the stent is not initially properly positioned would have been obvious since it was well known in this art to so retract and reposition stents for this reason. As to claim 53, Winston et al. fail to show Pellethane as the material for the inner tubular structure. However, using Pellethane as the material for the inner tubular structure would have been obvious since it is well known as a desirable material for this use as indicated on page 2, lines 8-10 of applicant's specification. The above well known in the art statements are taken to be admitted prior art because applicant failed to traverse the examiner's assertions (M.P.E.P. 2144.03).

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Claims 47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Bartholf et al. (2001/0034549) as applied to claims 11, 45, 48, 50-55 and 61-63 above, and further in view of Hofmann et al. (5,810,837). Winston et al. fail to disclose a gap between an external surface of the external tubular structure 14 and the inner surface of the outer tubular structure 20. However, Hofmann et al. teach that there should be a gap between the external surface of the external tubular structure 10 and the inner surface of the outer tubular structure 3 (the outer diameter C of member 10 is 4.5 mm while the inner diameter B of outer tubular structure 3 is 4.6 mm as indicated in col. 4, line 38) apparently in order to insure that the inner elongated structure 10, 9, 7 is able to slide relative to outer tubular structure 3 with minimal friction. It would have been obvious to provide such a gap between the Winston et al. external surface of the external tubular structure 14 and the inner surface of the outer tubular structure 20 so that it too would have this advantage.

Claims 56, 57, 59, 60, 64, 65, 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5,306,294) in view of Bartholf et al. (2001/0034549) as applied to claims 11, 45, 48, 50-55 and 61-63 above, and further in view

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of Burns (5,100,381). Winston et al. fail to disclose each subsequently proximal external structure 14 increasing in durometer. However, Burns teaches that the distal portion of a catheter should be more flexible than the proximal portion in order to allow the catheter to be advanced through the rather tortuous paths of the arteries while maintaining pushability (col. 2, lines 30-34 and col. 3, line 65 to col. 4, line 6). It would have been obvious to make the distal portion of the Winston et al. catheter 12 more flexible than the proximal portion so that it too would have this advantage. With this modification, the distal portion of the Winston et al. catheter 12 (which includes a distal flange 14) would be made of a material which is more flexible (with a low durometer) than a proximal portion of the catheter 12 (which includes a proximal flange 14) made of a high durometer, stiffer material.

Applicant's arguments filed Dec. 18, 2003 have been fully considered but they are not persuasive for the reasons set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703)308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht
1/22/04



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731